

Title: Administering the Human Papillomavirus Vaccine to Adolescents (Aged 9-14) - The Public Health Research Institute of India

SOP Number: 8, **Revision Number:** 0

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Prepared by: Dr. Devanshi Somaiya, Clinical Director, Cervical Cancer Prevention Program & Mr. Aarav Ahuja, Undergraduate Intern

Approved by: Dr. Raghavi Karanam, Chief of Clinical and Biomedical Services

Department/Function: Community Health/Clinical Medicine (Physicians, Nurses, Outreach workers, and appropriately trained interns/fellows)

1. PURPOSE:

- 1.1. This HPV vaccination SOP establishes clear and standardized guidelines for the storage, handling, safe administration, and accurate documentation of the Human Papillomavirus (HPV) vaccine.
- 1.2. This SOP details the procedures for HPV vaccination, including eligibility criteria, vaccination schedules, vaccine storage and handling, administration protocol, informed consent, documentation, management of adverse events, safety precautions, and communication with the child's parent or legal guardian.
- 1.3. Guidelines may evolve over time; national policies, if updated, supersede this document, and this document does not replace clinical judgment.

2. SCOPE:

- 2.1. This SOP applies to all healthcare professionals involved in the administration of the HPV vaccine at Public Health Research Institute of India, including physicians, nurses, health assistants, and trained interns/fellows.

3. DEFINITIONS AND ACRONYMS:

- 3.1. Human Papillomavirus (HPV) – HPV is a group of over 200 related viruses that infect the skin or mucous membranes; while most cause no symptoms, high-risk HPV types can lead to genital warts and various cancers (cervical, vaginal, vulvar, anal, penile, and throat).
- 3.2. Contraindications – conditions that can increase the risk for a serious adverse reaction; (see section 6.2 for HPV-vaccine specific contraindications).
- 3.3. Precautions – conditions that may heighten the risk of serious adverse reactions, interfere with accurate diagnosis, or reduce the effectiveness of the vaccine in generating immunity (see section 6.2 for HPV-vaccine specific precautions).
- 3.4. National Immunization Schedule (NIS) of India – This is a government-recommended schedule for administering vaccines as part of the Universal Immunization Programme (UIP).
- 3.5. Vaccine Information Statement (VIS) – A document providing essential information about a vaccine.

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- 3.6. Adverse Reaction – An unintended, harmful response to a medication that is administered at a normal dose.
- 3.7. GARDASIL 9-Valent HPV Vaccine – A recombinant vaccine developed by Merck to protect against nine different genotypes of HPV that cause cancer (Types 16, 18, 31, 33, 45, 52, and 58) and genital warts (Types 6 and 11).
- 3.8. GARDASIL 4-Valent HPV Vaccine – A vaccine developed by Merck to protect against four different genotypes of HPV that cause cancer and genital warts (Types 6, 11, 16, and 18).
- 3.9. CERVAVAC Vaccine – A quadrivalent recombinant vaccine developed by the Serum Institute of India (SII) that protects against the HPV genotypes of 6, 11, 16, and 18 and certain HPV-related cancers.
- 3.10. Lot/Batch Number – A unique code that helps to identify a particular batch of HPV vaccine for tracking, monitoring, and recall purposes.
- 3.11. Informed Consent – Voluntary permission given by a beneficiary, parent, or guardian after receiving clear information about a medical procedure, including its purpose, risks, and benefits.
- 3.12. Assent from the Child/adolescent receiving the vaccine - the affirmative agreement of a child or adolescent to receive a vaccine, distinct from the legal consent provided by a parent or guardian. While children under the age of majority (usually 18) generally cannot legally consent to medical procedures, they are encouraged to participate in the decision-making process through assent, which is often considered a moral, rather than legal, obligation to respect the child's evolving autonomy and views
- 3.13. Cold Chain – The system of equipment and set procedures to ensure vaccines remain within an optimal temperature range from the time of manufacturing until beneficiary administration.
- 3.14. PHRI – Public Health Research Institute of India
- 3.15. PLHIV- People living with HIV
- 3.16. WHO – World Health Organization
- 3.17. WHO SAGE- World Health Organization -Strategic Advisory Group of Experts on Immunization (SAGE)
- 3.18. FOGSI - Federation of Obstetric and Gynaecological Societies of India
- 3.19. PPE – Personal Protective Equipment

4. MATERIALS, REAGENTS & EQUIPMENT:

- 4.1. HPV Vaccine (ensure proper vial/pre-filled syringe is chosen based on the beneficiary's age group and dosage schedule)
- 4.2. Syringe and Needle (size depends on the beneficiary's age, weight, and the site of injection)
- 4.3. Alcohol Swabs (disinfection of vaccine site)
- 4.4. 1" Sterile Gauze/Cotton Balls
- 4.5. Adhesive Bandages/Band-Aids (Spot or Rectangular)
- 4.6. Gloves
- 4.7. Sharps Container (disposal of needles and syringes)
- 4.8. Waste Container (for disposal of general waste)
- 4.9. Disinfectant Wipes/Products for Surfaces/Hand Sanitizer
- 4.10. Documentation Sheet or Mobile Data Collection Tool

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- 4.11. Vaccine Preparation Tray
- 4.12. Vaccine Information Sheet (VIS)
- 4.13. Face Masks (optional)

5. ROLES & RESPONSIBILITIES

- 5.1. **Camp Coordination: Physician/Nurse:** Ensures availability of supplies (vaccines, syringes, PPE, and documentation materials), sets up vaccine station, oversees camp workflow.
- 5.2. **Prevaccination Tasks: Physician/Nurse/Outreach Worker/Trained Intern or Fellow:** Provides the VIS, answers questions, processes pre-vaccination paperwork, obtains consent from the parent/legal guardian, assent from the child/adolescent receiving the vaccine, ensures beneficiary's comfort and equipment readiness
- 5.3. **Vaccine Administration:**
 - 5.3.1. **Physician/ Trained Nurse:** Administers the HPV vaccine following standard safety protocols, ensures proper intramuscular technique, maintains hygiene/disposal procedures according to safety guidelines, and monitors for any adverse reaction post-vaccination. Provides follow-up information for subsequent doses, educates the parent/legal guardian on possible side effects, and provides proper documentation.
 - 5.3.2. **Physician/Trained Nurse/:** Manages any immediate adverse reactions during the post-vaccination observation period.

6. PROCEDURE

6.1. Dosing

- 6.1.1 Eligible age groups and sexes for HPV vaccination may vary by camp or clinic (as communicated by the camp manager), depending on the specific setting and project requirements. Vaccine-administering professionals must consult and adhere to the specific guidance provided for their respective camp or clinic.
- 6.1.2 The Federation of Obstetric and Gynecological Societies of India recommends HPV vaccination for individuals under 26; vaccination for beneficiaries aged 27-45 should be discussed with the beneficiary's clinician.
- 6.1.3 **Dosing Schedule for Beneficiaries, Females and Males, per WHO – SAGE and FOGSI 9-26+ Years of Age (*The dosing recommendations for WHO apply to approved vaccines (Gardasil-4, Gardasil-9, Cervavax, Cervarix, Cecolin, and Walrinvax. Currently, the recommended dosing for Serum Institute's Cervavac aligns with FOGSI recommendations. Any modification of these doses is at the administering entity's responsibility*)**

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Population Age	WHO SAGE Recommended HPV Vaccine Schedule	FOGSI Recommended HPV Vaccine Schedule
9-14 years of age WHO SAGE-Identified Priority Age Demographic	1 Dose - 0 months only OR 2 Doses - 0, 6-12 months (minimum interval of 6 months in between 1 st and 2 nd dose)	2 Doses - 0, 6-12 months (minimum interval of 6 months in between 1 st and 2 nd dose)
15-20 years of age	1 Dose - 0 months only OR 2 Doses - 0, 6-12 months (minimum interval of 6 months in between 1 st and 2 nd dose)	3 Doses - 0, 1-2, 6 months (minimum interval of 4 weeks between 1 st and 2 nd dose, 12 weeks between 2 nd and 3 rd dose, and 5 months between 1 st and 3 rd dose)
21-26 years of age	2 Doses - 0, 6-12 months (minimum interval of 6 months in between 1 st and 2 nd dose)	3 Doses - 0, 1-2, 6 months (minimum interval of 4 weeks between 1 st and 2 nd dose, 12 weeks between 2 nd and 3 rd dose, and 5 months between 1 st and 3 rd dose)
27-45 years of age	2 Doses - 0, 6-12 months (minimum interval of 6 months in between 1 st and 2 nd dose)	3 Doses - 0, 1-2, 6 months (minimum interval of 4 weeks between 1 st and 2 nd dose, 12 weeks between 2 nd and 3 rd dose, and 5 months between 1 st and 3 rd dose)

Data pertaining to the outcomes of single-dose HPV vaccination among males is currently limited according to information from the World Health Organization.

6.1.4 **For immunocompromised Males and Females**, includes people living with HIV, transplant recipients, primary immunodeficiencies, cancer therapy, autoimmune diseases on immunosuppression

Population Age	WHO SAGE Recommended HPV Vaccine Schedule	FOGSI Recommended HPV Vaccine Schedule
All ages	Minimum 2 Doses; 3 Doses Preferred 2 Doses - 0, 6-12 months (minimum interval of 6 months in between 1 st and 2 nd dose) 3 Doses - 0, 1-2, 6 months (minimum interval of 4 weeks between 1 st and 2 nd dose, 12 weeks between 2 nd and 3 rd , and 5 months between 1 st and 3 rd dose)	3-Dose Schedule Mandatory 0, 1-2, 6 months (minimum interval of 4 weeks between 1 st and 2 nd dose, 12 weeks between 2 nd and 3 rd dose, and 5 months between 1 st and 3 rd dose)

6.2 Contraindications and Precautions

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- 6.2.1 The HPV vaccine should not be administered to any beneficiary who has had a severe systemic or anaphylactic reaction to a previous dose of the HPV vaccine or any of its components; doing so is a contraindication to further HPV vaccination.
- 6.2.2 The Gardasil vaccines are manufactured using *Saccharomyces cerevisiae* (baker's yeast) and is contraindicated in individuals with a history of immediate hypersensitivity to yeast.
- 6.2.3 Moderate or severe acute illness, per a physician's judgement, (even if fever is not a symptom) is considered a precaution to HPV vaccination. Beneficiaries diagnosed with these illnesses should postpone vaccination until symptoms subside.
- 6.2.4 Mild acute illness (e.g., mild respiratory infection or diarrhea) is not a reason to delay vaccination.
- 6.2.5 Due to the lack of studies of HPV vaccination among pregnant women in clinical trials, if the beneficiary is pregnant, vaccination should be deferred until the pregnancy has concluded. If the beneficiary receives vaccination without knowing they are pregnant, they should not be alarmed and be instructed to contact the vaccine administering clinic (PHRII) or manufacturer.
- 6.2.6 Since HIV attacks CD4 cells, it weakens the immune system and makes it harder to fight infections. Because HPV is an opportunistic infection, it is more commonly recommended for HIV beneficiaries. Both the CDC and FOGSI recommend that PLHIV beneficiaries, starting at age 9, receive the HPV vaccine as soon as possible.
- 6.2.7 According to FOGSI, HPV vaccines are safe, well-tolerated, and suitable for immunocompromised individuals, including those with HIV.

6.3 **Prior to Vaccination: Physician/Nurse/Outreach Worker /Trained Intern /Fellow**

- 6.3.1 Review the beneficiary's vaccination history (should be documented in medical records, available personal vaccination cards, and/or immunization registries).
- 6.3.2 Refer to the tables in Sections 6.1.3 and 6.1.4 to determine whether the beneficiary meets the eligibility criteria for the HPV vaccine and the appropriate dosage schedule to follow.
- 6.3.3 Assess the beneficiary for precautions and contraindications, as outlined in Section 6.2. Detailed components of the vaccine to be administered should be provided to the beneficiary and should be consulted from the manufacturer's package insert.
 - Cervavac: Allergy or hypersensitivity to yeast or to any previous CERVAVAC vaccine dose, hypersensitivity to vaccine excipients (Polysorbate 80, L-Histidine)
 - Gardasil 9: Allergy or hypersensitivity to yeast or to any previous GARDASIL 9 or 4 vaccine dose, hypersensitivity to vaccine ingredients (HPV L1 Proteins, amorphous aluminum)

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hydroxyphosphate sulfate (AAHS), L-Histidine, Polysorbate 80, Sodium Borate)

- Gardasil 4: Allergy or hypersensitivity to yeast or to any previous GARDASIL 9 or 4 vaccine dose, hypersensitivity to vaccine ingredients (HPV L1 Proteins, AAHS, L-Histidine, Polysorbate 80, Sodium Borate)

- 6.3.4 Provide all participants (in the case of minors, their parent, guardian, or legal representative) with a copy of the most recently updated Vaccine Information Statement (VIS) and/or vaccine information leaflet and/or manufacturer inserts. Explain the disease, HPV, that the vaccination protects against, using simple terms and any visual references (as necessary to enhance explanation)
- 6.3.5 If the participant is a minor, obtain written informed consent from the parent/guardian and assent from the participant.
- 6.3.6 If the participant is an adult, obtain their written informed consent.
- 6.3.7 Determine the recommended date for the next dose, if applicable, per camp protocol. Inform the participant/parent/guardian of this date and encourage the participant/parent to bring the immunization card to all future visits.
- 6.3.8 Make sure all questions have been fully answered to the satisfaction of the parent/guardian and participants, and that participation is entirely voluntary.
- 6.3.9 Ensure epinephrine and other emergency medical supplies are available on site in the case of an adverse reaction (see Appendix D, Section 13.4 for a list of possible adverse reactions).

6.4 **During Vaccination: Physician/Nurse**

- 6.4.1 Confirm the vaccine name and type on the outer label.
- 6.4.2 Ensure the vaccine has been stored in the refrigerator at a temperature between 2 and 8 degrees up until the time of administration. Ensure the vaccine is not frozen (discard if frozen).
- 6.4.3 Confirm that the vaccine is administered prior to the expiration date on the vial.
- 6.4.4 Inspect the vaccine vial for cloudiness, discoloration, or particulate matter by holding it up to light. Discard the vial if any abnormalities are found. The solution should appear clear/colorless with a fine, uniform, white precipitate. Do not use if discolored or if particulates are present. Do not dilute/mix with other vaccines.
- 6.4.5 Maintain aseptic technique by washing hands with water and soap for at least 20-30 seconds. Wear clean gloves prior to handling the vaccine.
- 6.4.6 Reference the chart below to determine the needle gauge, needle length, and injection site required to most effectively administer the HPV vaccine.

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Injection site and needle size for Adolescents less than 18 years

Biological Sex and Age of Beneficiary	Needle Gauge	Needle Length	Injection Site
Children, 9-10 years of age	22-25 gauge	5/8 – 1 inch (16-25 mm)	Deltoid Muscle of Arm
		1-1.25 inches (25-32 mm)	Vastus lateralis Muscle of Anterolateral Thigh
Children, 11-18 years of age	22-25 gauge	5/8 – 1 inch (16-25 mm)	Deltoid Muscle of Arm
		1-1.25 inches (25-32 mm)	Vastus lateralis Muscle of Anterolateral Thigh

Injection site and needle size for adults older than 18 years

Biological Sex and Weight of Beneficiary	Needle Gauge	Needle Length	Injection Site
Female or male less < 59kg	22-25 gauge	5/8"*–1"	Deltoid Muscle of Arm
Arm muscle, female or male 59-69kg		1"	
Female 69-91kg		1"–1½"	
Male 69-118 kg		1½"	
Female 91+ kg			
Male 118+ kg			
Any weight	22-25 gauge	1"–1½"	Vastus lateralis Muscle of Anterolateral Thigh

****The preferred site for HPV injection is the deltoid muscle of the arm, but the vastus lateralis muscle of the anterolateral thigh can also be utilized.***

- 6.4.7 Ensure the vaccine preparation tray has been cleaned and wiped with disinfectant/hand sanitizer before use.
- 6.4.8 Set out required materials on a vaccine preparation tray: an appropriate vaccine vial, sterile syringes, needles (check gauge/length using table above), sterile alcohol preparation pads, and gauze/bandages.
- 6.4.9 Beneficiaries can be lying down or sitting while receiving the vaccine, as per their preference.
- 6.4.10 If younger children are receiving the vaccine or if they are anxious, have the parent hold the child gently and use distraction techniques, such as toys, breathing exercises, or talking.
- 6.4.11 Use an alcohol swab to thoroughly clean the appropriate area. Let the area dry completely to avoid stinging.
- 6.4.12 If using a single-dose vial, draw up the full 0.5 mL dose using a sterile syringe and needle and inject intramuscularly into the thickest part of

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- the beneficiary's muscle at a 90-degree angle, ensuring the full dose is delivered into the muscle tissue.
- 6.4.13 If using a multidose vial, both doses should be administered as soon as possible and no later than 6 hours after opening if stored at 2–8°C.
 - 6.4.14 If multiple vaccines are being given in the same arm, space injection sites at least one inch apart when possible.
 - 6.4.15 Once all the vaccine has been administered, withdraw the needle and dispose of it immediately into the sharp's container.
 - 6.4.16 Apply light pressure on the injection site with sterile gauze or cotton. Apply a bandage to the site.
 - 6.4.17 Have the beneficiary lie down or sit with support for at least 15 minutes to monitor for adverse reactions to the vaccine (see Appendix in section 13.4 for a full list). Encourage them to gently move their affected arm during the period to help prevent tightness.

6.5 **After Vaccination: Physician/Nurse/Health Assistant/Trained Intern/Fellow**

- 6.5.1 Inform the parent/guardian that mild redness, swelling, or pain at the site is common & that the child may experience symptoms such as fever, fatigue, and headache.
- 6.5.2 Please give the beneficiary and the parent/guardian the post-vaccination adverse effects pictorial instructions in Appendix 13.5
- 6.5.3 Paracetamol can be used to ease mild redness, swelling, pain, or fever as needed, but medical attention should be sought for a high fever, persistent pain, or symptoms of an allergic reaction.
- 6.5.4 Record the vaccination in clinical records and immunization cards/booklets. Record the date the vaccine was administered, the manufacturer/lot number, the site/route of vaccination, and the
- 6.5.5 Schedule the next round of vaccination(s) based on information in 6.1.3 and 6.1.4, in coordination with clinic/camp guidance.
- 6.5.6 Wipe down all high-touch surfaces the beneficiary interacted with disinfectant wipes and dispose of all materials except sharps in the standard trash bin.

7 **SAFETY AND PRECAUTIONS**

7.1 **Prior to Vaccination / General Precautions**

- 7.1.1 Pregnant beneficiaries should not be given the HPV vaccine until after pregnancy.
- 7.1.2 Lactating women are eligible to receive the HPV vaccine. Current evidence per FOGSI does not show an increased risk of adverse reactions (7.2.2 and 13.4) in either the mother or her child(ren).
- 7.1.3 Wash hands with soap and warm water thoroughly for 20-30 seconds with each new beneficiary.
- 7.1.4 Wear a new pair of clean gloves for each beneficiary to ensure personal and beneficiary's protection.

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- 7.1.5 This vaccine should be used cautiously in individuals with thrombocytopenia or bleeding disorders, as intramuscular injection may cause bleeding.
- 7.1.6 If multiple vaccines are administered simultaneously, the healthcare professional must use separate syringes and injection sites. They must also ensure the vaccines do not mix with one another.
- 7.1.7 It is recommended that beneficiaries complete all doses with the same vaccine type and manufacturer.
- 7.1.8 Store all HPV vaccines in the refrigerator at 2-8 °C. Dispose of the vaccine if frozen. Store all HPV vaccines in their original packaging to protect from light.
- 7.1.9 Since vaccination does not protect against all HPV types or existing infections, routine screening remains essential and should follow local guidelines.
- 7.1.10 A Vaccine Information Sheet (VIS) must be distributed to each beneficiary, parent, or guardian before vaccination.
- 7.2 Post-Vaccination**
- 7.2.1 To prevent the beneficiary from sustaining external injuries (e.g., head injuries), ensure they are lying down or seated with support as an alternative, during vaccination for 15 minutes post-vaccination.
- 7.2.2 Adverse Reactions – See Appendix 13.4 for a list of all possible adverse reactions and recommended treatments/courses of action. Common adverse reactions post-vaccination:

- Pain, Redness, and/or Swelling at the Injection Site
- Fever (temperature greater than 37.8 degrees C)
- Itching, Hives, or Rash at Injection Site
- Dizziness, Fatigue, and/or Headaches

Adverse reactions are common upon receiving the HPV vaccine and can range from being minor to serious. These reactions are similar to those of other vaccines and occur shortly after administration. Beneficiaries and their respective parents/legal guardians should always consult their physician/clinical provider when administering medications or seeking guidance.

7.3 Emergency Protocols

- 7.3.1 The healthcare professional should be called immediately if the beneficiary has any symptoms that persist beyond 48-72 hours/bother them.
- 7.3.2 The healthcare professional should be called if the beneficiary requires medical advice about side effects.
- 7.3.3 Keep medical emergency contact numbers available on site. Ensure this is also provided to the beneficiary.
- 7.3.4 Keep medical staff on site during the 15–30-minute post-vaccination monitoring period to monitor for high/low vital sign values or unusual

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symptoms (e.g. shortness of breath, joint pain, or muscular weakness) and take appropriate action/response.

7.3.5 Recommended medications and supplies to keep ready during HPV vaccination:

Medication	Purpose	When to Administer
(Cetirizine and Levocetirizine) Cetirizine: 6-11 years of age (5 to 10 mg OR 1-2 teaspoons once daily in syrup form) 12+ years of age (5-10 mg per dose orally) Levocetirizine: 6-11 years of age (2.5 mg orally once daily in the evening) 12+ years of age (5 mg orally once daily in the evening)	Mild Allergic Reactions (Itching, Rashes, Hives)	Upon first (early) symptoms of mild allergic reaction
Epinephrine 8-10 years (26-34.5 kg): 0.25-0.3 mL (or mg) 11-12 years (35-45 kg): 0.35-0.4 mL (or mg) 13-18 years (46 kg+): 0.5 mL (or mg) – maximum dose 18+ years: 0.3-0.5 mL (or mg) – 0.5 mL/mg is the maximum dose	Severe Allergic Reactions (Anaphylaxis)	Immediately if severe signs of anaphylaxis appear (e.g. difficulty breathing, severe rash, swelling)
Acetaminophen/Paracetamol 9-10 years (27-32 kg): 300-400 mg 11 years+ (43.5 kg+): 500 mg Every 6hrs, max dose 2000mg/day Ibuprofen 9-10 years (27-32 kg): 250 mg 11 years (32.7-43.1 kg): 300 mg 12 years+ (43.5 kg+): 200-400 mg Max 400 mg twice daily	Reduce pain, fever, and/or discomfort post-vaccination	If the beneficiary reports more serious pain/swelling and/or if the beneficiary exhibits a temperature greater than 37 degrees C (fever)

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Ice/Cold Packs	Reduce swelling and pain at the injection site	Apply if the beneficiary complains of slight local pain/swelling after vaccination.
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8 QUALITY CONTROL AND ASSURANCE

- 8.1 Ensure multi-dose vials are discarded if not used within 6 hours of opening.
- 8.2 Vaccine's name, batch number, and expiration date should always be verified prior to administration.
- 8.3 Dispose of vials that are expired, improperly stored, or exhibit signs of cross-contamination.
- 8.4 Only trained and certified healthcare professionals such as nurses, physicians, or other designated vaccinators should handle and administer the vaccine. Regular refresher training and competency assessments must be conducted. See Section 13.1 (retrain, if necessary).
- 8.5 Ensure all waste materials are correctly disposed of in biohazard vs. regular trash containers. Verify that all surfaces in contact with the beneficiary are sanitized in between vaccinations.
- 8.6 Create a hospital/clinic/camp-wide protocol to manage and report post-vaccination Adverse Events. These must be documented and reviewed regularly.
- 8.7 Random, regular audits of technique and documentation must be conducted.

9 DOCUMENTATION AND RECORDKEEPING: Physician/Nurse/Health Assistant/Trained Intern/Fellow

- 9.1 Record vaccination records in the hospital/clinical/camp files (process and paperwork vary) or electronic/digital records. Beneficiary name, date of birth, date/time of vaccination, vaccine name, site of injection, name of administrator, etc., should all be noted within these files and stored securely.
- 9.2 **Provide the beneficiary's vaccine record and information on follow-up vaccine doses as indicated** (use the dosing schedule in 6.1.3 and 6.1.4).
- 9.3 Maintain confidentiality via India's data protection and informed consent laws: Digital Personal Data Protection Act, 2023 (India) & Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations 2002
 - 9.3.1 Maintenance of Medical Records
 - All vaccine providers must maintain the vaccination records of their beneficiaries for at least 3 years from the start of vaccination.
 - Beneficiaries must receive access to their medical records within 72 hours of requesting them from their medical provider.

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- Paper records should be kept in locked cabinets with access restricted to authorized personnel only.
- All digital records are to be stored on password-protected systems,
- When reporting data for clinical research, all data must be anonymized
- Any data breach/confidentiality breach should be immediately reported to PHRII leadership.

10 COMPETENCY AND PROFICIENCY

- 10.1 All personnel assigned to this SOP must receive training from an authorized trainer or supervisor before independently administering the HPV vaccine.
- 10.2 Competency will be regularly verified through assessment methods such as direct observation, skills checklists, and written/oral evaluations.
- 10.3 Checklist for Safe Vaccine Storage and Handling — Appendix 13.1
- 10.4 Skills Checklist for Vaccine Administration — Appendix 13.2
- 10.5 Vaccine Storage and Handling Toolkit) – Appendix 13.3
- 10.6 Reassessment of competency will occur at least every six months to one year or when major revisions to the SOP are implemented.
- 10.7 Personnel must demonstrate both knowledge of the SOP content and the ability to perform the tasks safely and accurately. However, hospital/clinical/camp administration should regularly audit for vaccine administration competency.
- 10.8 Staff who do not meet competency requirements must undergo retraining and reassessment prior to resuming responsibilities covered by this SOP.
- 10.9 All staff must understand how to document vaccine records properly, prepare beneficiaries for vaccination, maintain aseptic technique, obtain informed consent from the parent or guardian, informed assent from the beneficiary, and follow each step/safety precaution outlined in the administration protocol.
- 10.10 Trained staff must approve new staff before they perform any vaccination related tasks, and all new staff must sign this SOP to confirm understanding.

11 REVIEW AND REVISION:

- 11.1 This SOP will be reviewed every 1–2 years, as prescribed by the authorizing entity, or sooner if new evidence and guidelines become available.

12 REFERENCES

- 12.1 Centers for Disease Control and Prevention. (2024, June 18). *Vaccine administration*.
<https://www.cdc.gov/vaccines/hcp/imz-best-practices/vaccine-administration.html>
- 12.2 Centers for Disease Control and Prevention. (2025). *Vaccine administration: After giving vaccine*.
<https://www.cdc.gov/vaccines/hcp/administration/after.html>

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- 12.3 Centers for Disease Control and Prevention. (2024, July 25). *Contraindications and precautions*.
<https://www.cdc.gov/vaccines/hcp/imz-best-practices/contraindications-precautions.html>
- 12.4 Centers for Disease Control and Prevention. (2025, June 24). *Vaccine administration: During vaccination*.
<https://www.cdc.gov/vaccines/hcp/administration/during.html>
- 12.5 Centers for Disease Control and Prevention. (2021, November 16). *HPV vaccine administration*.
<https://www.cdc.gov/vaccines/vpd/hpv/hcp/administration.html>
- 12.6 Centers for Disease Control and Prevention. (N.D.). *Vaccine administration: Intramuscular (IM) injection children 7 through 18 years of age*
<https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-children.pdf>
- 12.7 CERVAVAC®. (2022, December 31). *CERVAVAC® quadrivalent human papillomavirus (Serotype 6, 11, 16 & 18) vaccine recombinant*. Central Drugs Standard Control Organisation Government of India.
<https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadSmPC/qHPV%20-%20SmPC%202022.pdf>
- 12.8 CERVAVAC. (2022, December 31). *CERVAVAC® quadrivalent human papillomavirus (Serotype 6, 11, 16 & 18) vaccine recombinant: Summary of product characteristics*. Central Drugs Standard Control Organization, Government of India.
<https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadSmPC/qHPV%20-%20SmPC%202022.pdf>
- 12.9 Directorate of Public Health and Preventive Medicine. (2024). *UWIN Frequently Asked Questions*.
https://portal.tndphpm.com/tndphpmfiles/1747215582_english.pdf
- 12.10 Immunize.org. (2023). *Medical management of vaccine reactions in children and teens*.
<https://www.immunize.org/wp-content/uploads/catg.d/p3082a.pdf>
- 12.11 Immunize.org. (2023, April 19). *Medical management of vaccine reactions in adults in a community setting*.
<https://www.immunize.org/wp-content/uploads/catg.d/p3082.pdf>
- 12.12 Immunize.org. (2025, May 19). *Standing orders for administering human papillomavirus vaccine to children and teens*.
<https://www.immunize.org/wp-content/uploads/catg.d/p3090.pdf>
- 12.13 Immunize.org. (2025, January 16). *Supplies you may need at an immunization clinic*.
<https://www.immunize.org/wp-content/uploads/catg.d/p3046.pdf>
- 12.14 Medical Council of India. (2002, April 6). *Indian medical council (professional conduct, etiquette and ethics) regulations, 2002*.
<https://www.nmc.org.in/wp-content/uploads/2017/10/Ethics-Regulations-2002.pdf>

SOP No. 8	Administering the Human Papillomavirus Vaccine to Adolescents (Aged 9-14) Standard Operating Procedure - The Public Health Research Institute of India		
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- 12.15 Merck. (2025, March). *Highlights of prescribing information: Gardasil 9 (Human papillomavirus 9-valent vaccine, recombinant)*.
https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf
- 12.16 Merck. (2025, April). *Patient Information about GARDASIL 4®*.
https://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_ppi.pdf
- 12.17 Merck. (2025, March). *Patient information about GARDASIL®9*.
https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_ppi.pdf
- 12.18 Ministry of Law and Justice of India. (2023, August 11). *The Digital Personal Data Protection Act, 2023*.
<https://www.meity.gov.in/static/uploads/2024/06/2bf1f0e9f04e6fb4f8fef35e82c42aa5.pdf>
- 12.19 Motrin. (n.d.). *Motrin (Ibuprofen) infant and children's dosage chart*.
<https://www.motrin.com/children-infants/dosing-charts>
- 12.20 Naqvi, A. (2024, May 6). *Cetirizine*. *StatPearls [Internet]*.
<https://www.ncbi.nlm.nih.gov/books/NBK549776/>
- 12.21 National Health Mission, Ministry of Health and Family Welfare, Government of India. (2024). *National quality assurance standards for public health facilities*.
https://qps.nhsrindia.org/sites/default/files/2024-05/National%20Quality%20Assurance%20Standards%202024%20_revised.pdf
- 12.22 National Institutes of Health. (2024, November 4). *HIV and human papillomavirus*.
<https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-and-human-papillomavirus>
- 12.23 The Federation of Obstetric and Gynaecological Societies of India. (2024, June 18). *FOGSI GCPR on prevention and management of cervical cancer – June 2024*.
<https://www.fogsi.org/fogsi-gcpr-on-prevention-and-management-of-cervical-cancer-june-2024/>
- 12.24 Savoy, M. L., & Vivian, E. M. (2025, July). *Human papillomavirus (HPV) vaccine - infectious diseases*. MSD Manual Professional Edition.
<https://www.msdmanuals.com/professional/infectious-diseases/immunization/human-papillomavirus-hpv-vaccine>
- 12.25 Tabsul. (2025, December 15). *Levocetirizine 5mg tablets - comprehensive information*. <https://tabsul.com/medicine/levocetirizine-5mg-tablets>
- 12.26 Tylenol. (n.d.-a). *Dosing chart for children & infants Tylenol*. Tylenol.
<https://www.tylenol.com/safety-dosing/dosage-for-children-infants>
- 12.27 Tylenol. (n.d.-b). *Proper Tylenol dosage for adults*. Tylenol.
<https://www.tylenol.com/safety-dosing/dosage-for-children-infants>
- 12.28 World Health Organization. (2022, December 16). *Human papillomavirus vaccines: WHO position paper (2022 update)*.
<https://iris.who.int/server/api/core/bitstreams/182d51d2-6d08-4963-a643-43d4bc843189/content>

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13 APPENDICES

13.1 Appendix A – Skills Checklist for Vaccine Administration

Vaccine Administration Skills competency assessment should be performed using the *Skills Checklist for Vaccine Administration* attached below. This has also been adapted from a checklist provided by Immunize.org, available at <https://www.immunize.org/wp-content/uploads/catg.d/p7010.pdf> This checklist serves as an evaluation tool to ensure healthcare staff are competent in administering immunizations safely and effectively resources in India.

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13.2 Appendix B - Vaccine Storage and Handling Toolkit
Vaccine Storage and Handling Toolkit is a training created by the CDC to standardize vaccine administration/storage policies

Training Access:

<https://www.cdc.gov/vaccines/hcp/downloads/storage-handling-toolkit.pdf>

COLD CHAIN PROCEDURES ROUTINE VACCINE MAINTENANCE



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1. Storage Equipment Checks

Step	Action	Responsibility	Documentation/Notes
Verify Equipment Function	- Physically inspect the fridge/freezer (check door seals for wear-and-tear, strange noises, frost build-up, or error codes) - Ensure the appliance is powered "on" and check that the indicator lights are operational - Fridge must be purpose-built or of pharmaceutical grade designed to refrigerate/freeze vaccines	Vaccine Storage Staff/ Facility Maintenance Team	Daily Equipment Check Log: Log specific details (date, time, and any inspection irregularities) of the inspection. Any irregularities should be escalated for follow-up by other personnel.
Temperature Monitoring Devices	- Ensure temperature-monitoring devices are functioning (digital loggers, thermometers) - Verify that alarm systems are set to notify staff if temperature deviate outside of the recommended range - Ensure that loggers are calibrated using an industry-standard thermometer regularly - Keep this data for at least three years for long term analysis	Vaccine Storage Staff/ Facility Maintenance Team	Calibration Log: Track calibration dates and results for each device (when applicable). Log any document battery replacement dates and/or found issues
Backup Equipment	Verify that backup refrigeration units are available and in proper working condition (should be pre-cooled and ready for use) –	Vaccine Storage Staff/ Facility Maintenance Team	Power/Backup Equipment Log: Document any notes/irregularities pertaining to backup equipment

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	should also be calibrated regularly • Back-up power systems are operational • Insulated coolers with ice packs readily available in case of emergency storage needs		availability, condition, and tests.
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2. Temperature Monitoring

Step	Action	Responsibility	Documentation/Notes
Twice-Daily Temperature Checks	• Record the temperature of the storage unit at both the start and end of each workday – thermometer should be placed at the center of the storage unit • Ensure that the refrigerator temperature sits between 2 and 8 degrees C and that the freezer is between -50- and -15-degrees C.	Vaccine Storage Staff/ Facility Maintenance Team	Temperature Monitoring Log Sheet: Record temperature at beginning and end of workday, date, time, name of person who checked temperature, any actions taken/need to be taken
Temperature Range Compliance	• Review recorded temperatures from both manual checks and data loggers (ensure in recommended vaccine storage ranges) • Identify the cause of any possible deviations and document any corrective actions taken	Vaccine Storage Staff/ Facility Maintenance Team	Deviation Log: Record any affected batch numbers, storage unit type, cause/duration of deviation, and any actions taken.
Supervisor Verification	• Supervisors must review temperature logs at the end of each day to verify temperatures within acceptable range and that any deviations are properly addressed • Conduct a follow-up investigation if any deviations found • Supervisor must sign off on the log to confirm review	Supervisor	Deviation Log: Supervisor signs and dates confirming the deviation log has been reviewed. Additional notes are added if further investigation required.
Vaccine Storage	• Vaccines must be stored in their original packaging with lids tightly closed until ready for administration • Food/beverage cannot be stored in the same storage unit as vaccines	Vaccine Storage Staff/ Facility Maintenance Team	Daily Equipment Check Log: Log specific details (date, time, and any inspection irregularities) of the inspection. Any irregularities should be

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			escalated for follow-up by other personnel.
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3. Vaccine Storage Practices

Organize/ Rotate Stock	- Organize vaccines using the First-In-First-Out method (place newer stock behind older stock) - Check expiry dates weekly to ensure older vaccines are used first (review inventory regularly) - Each batch must be labeled with the respective lot number and expiration date - Order and stock only the amount of vaccines required for patient needs, check shipments for any signs of damage	Vaccine Storage Staff/ Facility Maintenance Team	Inventory Log: Record batch numbers, expiration dates, and any actions related to stock rotation.
Appropriate Storage Placement	- Vaccine storage units should be placed in a well-ventilated room, leaving space between units, ceiling, and any wall – place vaccines properly in the fridge/freezer - Vaccines should sit above the floor (on shelves or trays) - Air vents/motors should not be blocked to allow for consistent temperature distribution - Do not stack boxes or trays too high to prevent blockage of airflow	Vaccine Storage Staff/ Facility Maintenance Team	Inventory Log: Track proper placement and organization of vaccines. Any inappropriate actions should be noted.

4. Preventive Maintenance

Clean/ Defrost Units	- Clean the fridge and freezer units weekly, using approved cleaning supplies (wipe down shelves, door seals, interior) - Inspect door seals and door hinges to ensure that the door opens and closes smoothly (prevent cold air from leaving) - If frost builds up, defrost the freezer according to the manufacturer's instructions. If the frost exceeds 1 cm, defrost immediately (store the	Vaccine Storage Staff/ Facility Maintenance Team	Cleaning Log: Record cleaning date, staff name, and any issue with the vaccines/storage units. If defrosting is required, not the amount of frost removed and time spent.
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	vaccines temporarily in another unit with required conditions)		
Equipment Inspection	- Schedule a certified technician to inspect the refrigeration units regularly. - Check storage unit door seals, door hinges, unit coils, and the inside of units regularly	Vaccine Storage Staff/ Facility Maintenance Team	Maintenance Log: Track dates of inspection, technician details, and any actions taken.
Power Supply	- Only one storage unit is to be plugged in per electrical outlet (avoid fire hazards or power shortage) - Safety-lock plug or outlet cover to prevent the storage unit from being unplugged “Do not unplug” warning signs should be placed around outlets to warn staff, fuses and circuit breakers should have similar messaging	Vaccine Storage Staff/ Facility Maintenance Team	Power/Backup Equipment Log: Document any notes/irregularities pertaining to power equipment availability, condition, and tests.

5. Staff Training and Education

Initial Staff Training	- Conduct initial staff training of all new staff on the importance of cold chain management, temperature monitoring, and proper vaccine handling. - Train staff on up-to-date storage and handling SOPs & emergency SOPs	Training Coordinator	Training Log: Keep a record of training dates, staff names, and content covered in training session
Regular Refresher Training	- Conduct regular refresher training to ensure staff competency and to update staff on any changes in procedure or regulations regarding cold chain maintenance - Review any previous cases/incidents to reinforce best practices - Address any gaps or deviations from protocol immediately - Ensure all records (Sections 1-5) are kept for at least three years and are available in digital/manual format	Supervisor	Training Log: Keep a record of training dates, staff names, and content covered in training session Compliance Audit Log: Record any staff compliance issues, corrective actions taken, and recommended follow-up actions

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COLD CHAIN PROCEDURES EMERGENCY VACCINE MAINTENANCE RESPONSE



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1. Storage Equipment Checks

Step	Action	Responsibility	Documentation/Notes
Twice-Daily Temperature Checks	- Record room temperature (if possible) and temperature of storage unit as soon as the power goes out - Record minimum and maximum temperatures reached inside the unit - Ensure that the refrigerator temperature sits between 2 and 8 degrees C and that the freezer is between -50- and -15-degrees C. - Set alarms/alerts for specific temperature thresholds	Vaccine Storage Staff/ Facility Maintenance Team	Alarm Log: Record the time, temperature, and action taken when the alert is triggered
Continuous Monitoring	- Review recorded temperatures from both manual checks and data loggers (ensure in recommended vaccine storage ranges) - Identify the cause of any possible deviations and document any corrective actions taken	Vaccine Storage Staff/ Facility Maintenance Team	Deviation Log: Record any affected batch numbers, storage unit type, cause/duration of deviation, and any actions taken.
Identifying Deviation	- Review data loggers and compare temperatures with acceptable ranges - If deviations are found, flag them immediately for investigation	Vaccine Storage Staff/ Facility Maintenance Team	Deviation Record: Highlight temperature deviations in the log and include any potential causes

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2. Immediate Response Actions

Step	Action	Responsibility	Documentation/Notes
Assess Affected Vaccines	- Identify which vaccine batches/lots are affected by the temperature deviation by checking batch numbers and expiry dates. - Determine any potential damage based on the amount of time vaccine left out of range and the manufacturer-specific guidelines	Vaccine Storage Staff/ Facility Maintenance Team	Emergency Log: Record affected vaccine batch numbers, expiry dates, time of temperature excursion, initial physical assessment
Transfer Vaccines to Backup Storage	- Immediately transfer the affected vaccines to a backup fridge/freezer or use an insulated cooler with ice packs for temporary storage (ensure backup is within correct temperature range) - Permitted backup units per CDC: portal vaccine refrigerator/freezer, qualified container/packout, conditioned water bottle transport system, and manufacturer's original shipping container (last resort) - Contact alternative storage facility	Vaccine Storage Staff/ Facility Maintenance Team	Deviation Log: Record any affected batch numbers, storage unit type, cause/duration of deviation, and any actions taken.
Limit Access	- Restrict access to any affected storage unit to only authorized personnel. - Mark affected vaccines with "Do Not Use" labels until they can be assessed for usability	Supervisor	Restricted Access Log: Note who has access and the period of restricted access

3. Risk Assessment and Manufacturer Guidance

Consult Manufacturer Guidelines	- Review manufacturer-specific guidelines to check if the vaccines are still usable after temperature deviation (some vaccines still stable outside recommended ranges for limited periods) - Assess potential impact on vaccine potency (duration of	Supervisor	Vaccine Stability Log: Record details of the manufacturer's recommendations regarding temperature excursions for each affected vaccine. Document which vaccines are affected.
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	deviation, temperature range, vaccine type)		
Decision Making	- Based on manufacturer guidelines, decide whether the affected vaccines can be used or should be discarded. - In the case of any uncertainty, the manufacturer should be immediately contacted.	Supervisor	Decision Log: Document any decisions made (use or discard), including the time, temperature excursion details, and reason for decision

4. Team Communication

Notify Supervisor	- Inform the supervisor immediately once a temperature deviation is detected. - Provide them with all relevant information (affected vaccines, temperature deviation details, immediate actions taken)	Vaccine Storage Staff/ Facility Maintenance Team	Vaccine Stability Log: Record time and details of notification. Include the supervisor's response.
Report to Health Authorities	- Notify national health authorities as required by local protocols. - Provide them with a full report on the incident, including affected vaccine, duration of temperature deviation, further actions taken.	Supervisor	Regulatory Reporting Log: Document the time of notification, details provide, and authorities contacted.
Inform External Stakeholders	- Notify stakeholders (other facility staff and external partners) about the incident - Reschedule any appointments if vaccine schedules are affected	Supervisor	Stakeholder Communication

5. Recovery and Preventive Measures

Return Vaccines to Proper Storage	Return the vaccines to the appropriate storage unit once the temperature has stabilized within the acceptable range.	Vaccine Storage Staff/ Facility Maintenance Team	Recovery Log: Document time of return to proper storage, the condition of vaccines upon return, and temperature during the recovery process
Equipment Repair	Ensure equipment is sent for immediate repair/replacement, schedule maintenance as necessary	Supervisor	Root Cause Analysis Report: Document findings, corrective actions, and preventive measures taken.

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	Complete a root cause analysis to identify the cause of the temperature deviation, address the cause to prevent future incidents (upgrading equipment, improving SOP protocols)		
Review Emergency Protocols	- Review and update emergency cold chain protocols based on the incident to prevent reoccurrence. - Ensure all staff are trained on the updated procedures - Ensure all records (Sections 1-5) are kept for at least three years and are available in digital/manual format	Supervisor	Update SOPs & Ensure Regular Staff Training

Key Notes:

- Manufacturer guidelines must always be consulted first when assessing the impact of temperature excursions
- Vaccines that fall outside of the recommended temperature range cannot be used without consulting experts, authorities, and the manufacturer.
- Documentation should be thorough at every stage of the response
- If there are long-term temperature excursions, vaccines should be discarded as prolonged out-of-range temperatures can render vaccines ineffective.

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Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies



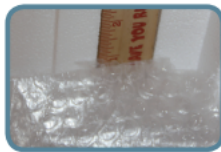
Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^\circ\text{F}$ ($\pm 0.5^\circ\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



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Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.

NOTE:
This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

8. Temperature Monitoring Device Display (on lid)

7. Conditioned Water Bottles

6. Cardboard Sheet

5. Bubble wrap, packing foam, or Styrofoam™

4. Vaccines, Diluents, and Temperature Monitoring Device Probe

3. Bubble wrap, packing foam, or Styrofoam™

2. Cardboard Sheet

1. Conditioned Water Bottles

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

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13.3 Appendix C Checklist for Vaccine Handling and Storage

Vaccine Storage/Handling competency assessment should be performed using the *Checklist for Safe Vaccine Storage and Handling* provided by Immunize.org, a United States-based 501c3 nonprofit organization that partners with the CDC to promote. This checklist ensures that all vaccines like HPV remain effective by maintaining proper vaccine temperatures and following accurate protocols (properly safeguarding vaccine supply). Note that because this is made by a US-based health agency, not all resources will reflect laws/available resources in India. Checklist Access: <https://www.immunize.org/wp-content/uploads/catg.d/p3035.pdf>

13.4 Appendix D – Adverse Reactions and their management

Body System Associated with Adverse Reaction	Frequency of Reaction	Adverse Reactions	Management of Reaction
Nervous System	Common	Headache	Have the beneficiary lie flat and loosen tight clothing. Keep the airway open and apply a cool, damp cloth to the face and neck. Medical professional should monitor closely until fully recovered. Acetaminophen or Aspirin.
	Occasional	Dizziness / Weakness	
	Occasional	Fatigue	
	Rare	Confusion	
	Rare	Seizure	Alert the lead medical professional on-site and dial 112.
Gastrointestinal System	Rare	Nausea / Vomiting	Have the beneficiary lie flat and loosen tight clothing. Keep the airway open and apply a cool, damp cloth to the face and neck. Medical professional should monitor closely until fully recovered. Offer beneficiary small sips of water and oral rehydration solution (ORS).

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Integumentary System (Skin)	Rare	Diarrhea	Oral Rehydration Solution (ORS) to relieve weakness from diarrhea
	Rare	Abdominal Pain	
	Common	Injection Site Pruritus (Itching)	Sign of Anaphylaxis – Alert the lead medical professional on-site and assess vital signs/overall condition of beneficiary. Consider treatment of either epinephrine or antihistamines.
	Common	Hives / Lump at Injection Site	
	Rare	Skin Infection	
Musculoskeletal System	Occasional	Slight or Continuous Bleeding	Slight – Apply an adhesive compress with pressure over the injection site.
			Continuous – Place gauze pads on the site, apply firm pressure, and elevate the arm above heart level.
	Occasional	Pain in Extremity	Place a wet cloth on the injection site. Consider taking medication for pain (acetaminophen) or itching (antihistamine) if necessary.
	Common	Injection Site Erythema (Skin Redness)	
	Rare	Joint Pain	Acetaminophen or Ibuprofen
	Rare	Muscle Weakness/ Aching Muscles	
General Disorders / Other Symptoms	Occasional	Injection Site Pain/Bruising/Bleeding	Place a wet cloth on the injection site. Consider taking medication for pain (acetaminophen) or itching (antihistamine) if necessary.
	Occasional	Injection Site Swelling	
	Common	Pyrexia (Fever) / Chills	Acetaminophen or Ibuprofen
	Occasional	Sore Throat	Sign of Anaphylaxis – Alert the lead medical professional on-site and

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	Rare	Swollen Glands (Neck, Armpit, Groin)	assess vital signs/overall condition of beneficiary. Consider treatment of either epinephrine or antihistamines.
	Rare	Chest / Leg Pain	Acetaminophen or Ibuprofen
	Rare	Generally Feeling Unwell	Rest, Hydration, and Healthy Diet
	Rare	Shortness of Breath	Sign of Anaphylaxis – Alert the lead medical professional on-site and assess vital signs/overall condition of beneficiary. Consider treatment of either epinephrine or antihistamines.

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13.5 Post Vaccination Adverse Effects Pictorial Instructions

Use one of the following to disseminate after vaccination



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13.6 Quick Workflow Chart for HPV Vaccination

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STEP 1: PATIENT REGISTRATION/ARRIVAL	STEP 2: PRE-VACCINATION SCREENING
☐ Appointment Verification (verify patient identity, check scheduled appointment/walk-in eligibility) ☐ Initial Screening - Check age group/risk category/prior vaccination status - Identify special populations (pregnant, immunocompromised, elderly) ☐ Patient Education & Consent (provide clear information on vaccine type/side effects/benefits via Vaccine Information Statement & obtain informed consent and/or assent)	☐ Medical History Review (previous vaccinations, immune status, allergies) ☐ Current Health Assessment ☐ Vaccine-Specific Considerations (contraindications and precautions)
STEP 3: VACCINE PREPARATION	STEP 4: VACCINE ADMINISTRATION
☐ Select & confirm correct vaccine type and formulation chosen ☐ Check vial for integrity, expiration, and proper cold chain maintenance (correct storage temperature) ☐ Aseptic Technique (wash hands with water and soap for at least 20-30 seconds, wear clean gloves prior to handling vaccination supplies) ☐ Verify dose calculation and correct administration route ☐ Ensure vaccination preparation tray has been disinfected and that all vaccine supplies are sterile.	☐ Verify patient identity (full name and DOB) and vaccine type again ☐ Explain procedure and site of injection ☐ Use an alcohol swab to thoroughly clean the appropriate area. Let the area dry completely to avoid stinging. ☐ Draw up the desired vaccine dose using a sterile syringe and needle and inject intramuscularly into the thickest part of the muscle at a 90-degree angle. ☐ Withdraw the needle and dispose of all contaminated supplies/sharps/vaccine vials immediately into the designated biomedical waste container(s) (e.g. sharps container). ☐ Apply gentle pressure/bandage if needed
STEP 5: POST-VACCINATION & DOCUMENTATION	STEP 6: DOCUMENTATION / FOLLOW-UP
☐ Observe beneficiary for 15-30 minutes (monitor for adverse reactions) ☐ Inform the beneficiary (and parent/guardian if applicable) about common symptoms (adverse events) and available treatments/remedies ☐ Provide patients with contact information to report any experienced adverse events	☐ Schedule the next round of vaccination in accordance with the vaccine-specific schedule and in coordination with camp/clinic procedures. ☐ Provide the beneficiary with a copy of their vaccination record along with information on follow-up doses.

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☐ Record the vaccine details in both internal clinical records and immunization cards/booklets ☐ For children , maintain online vaccine records through the U-WIN portal .	☐ Wipe down all surfaces the beneficiary interacted with and dispose of all materials except sharps in the standard trash bin.
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Prepared By: Dr. Devanshi Somaiya

Title: Director, Cervical Cancer Prevention Center. _____ Signature

Approved By: Dr. Raghavi Karanam

Title: Head of Clinical and Biomedical Services. _____ Signature

Effective Date: _____ Review Date: _____

Acknowledgment of Review and Agreement to Comply

The following personnel have reviewed this SOP. By signing below, the undersigned confirm that they have read, understood, and agree to follow the above SOP to the best of their ability.

They affirm that:

- All questions have been clarified and answered to their satisfaction.
- They accept responsibility to comply with the SOP as written.
- They will bring any new queries or uncertainties to their supervisor, and if needed, escalate up the chain of command until the question is resolved to their satisfaction.

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NO	Name	Title/Position	Signature.	Date
1.	Mrs. Poornima Jayakrishna	Chief Administrative Officer		
2.	Dr. Purnima Madhivanan	Founder, Chief Research Director		
3.	Dr. Kiranmayee Muralidhar	Research Physician		
4.	Dr. Raghavi Karnam	Clinic Chief Physician		
5.	Ms. Kavitha Chandrappa	Director, Laboratory		
6.	Ms. Anisa Khan	Associate Director, Laboratory		
7.	Dr. Devanshi Somaiya	Director, Cervical Cancer Prevention Program		
8.	Mrs. Rashmi	Staff Supervisor		
9.				
10.				
11.				
12.				
13.				
14.				

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No.	Name	Title	Signature	Date
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